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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,772	08/18/2003	Meir Rosenberg	022719-0046	3663

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EXAMINER	
HOEKSTRA, JEFFREY GERBEN	
ART UNIT	PAPER NUMBER
3736	

NOTIFICATION DATE	DELIVERY MODE
03/13/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

Office Action Summary	Application No.	Applicant(s)	
	10/642,772	ROSENBERG, MEIR	
	Examiner	Art Unit	
	JEFFREY G. HOEKSTRA	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25 and 27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/02/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice of Amendment

1. In response to the amendment filed on 01/02/2008, amended claim(s) 18 and canceled claim(s) 26 is/are acknowledged. The following reiterated grounds of rejection are set forth:

Information Disclosure Statement

2. The information disclosure statement(s) (IDS) submitted on 01/02/2008 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement(s).

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-11, 13, 15-25, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fonger et al (US 5,291,896) in view of Purdy et al (US 2003/0097082 A1).

5. For claims 1 and 18, Fonger et al discloses a catheter drainage system, comprising: an elongated tube, or catheter, 12 including a distally disposed solid state pressure transducing sensor 14 (column 6 lines 1-41) as best seen in Figures 1 and 2 and (b) said sensor functions to measure pressure adjacent the external surface of the distal-most end of the catheter (column 5 lines 4-20 and column 6 lines 1-41), further including at least one wire 24 distally coupled to the sensor and proximally mated to an

apparatus for electrical powering or communicating that extends along the length of the catheter in fluid isolation from the inner lumen 40 and wherein the at least one wire being proximally separable from the elongated tube through a slit 46 such that the tube length is selectively adjustable (column 2 lines 30-35 and column 4 lines 32-44). Furthermore, the slit 46 extends through the outer wall 15 of the tube 12 into the second lumen 42 such that the at least one wire can be partially removed to adjust the tube length.

6. For claims 2 and 11, Fonger et al discloses the at least one wire 24 disposed within a second lumen 42 isolated from the first and wherein the slit 46 extends into the second lumen).

7. For claim 3, 6-10, and 21-24, Fonger et al discloses a slit 46 extending through the outer wall 15 of the tube 12 into the second lumen 42 such that the tube length is selectively adjustable (column 4 lines 32-44). The slit 46 is configured such that the at least one wire can be partially removed to adjust the tube length and when said wire(s) is/are inserted they are in substantial fluid isolation via the sealing action of the polymer. The slit 46 is configured (column 4 lines 6-10) to extend along a distance less than the length of the catheter and less than about one half the length of the catheter as best seen in Figure 1.

8. For claims 4 and 19, Fonger et al discloses a first lumen diameter greater than the second lumen diameter (column 3 lines 60-66).

9. For claims 5 and 20, Fonger et al discloses multiple secondary lumens 84,86,88,90 formed within an invagination of the outer tube wall 12 as best seen in Figure 7.

10. For claims 13 and 25, Fonger et al discloses the use of a flexible, biocompatible polymer (column 3 lines 41-42).

11. For claims 15-17 and 26-27, Fonger et al discloses a distally disposed pressure sensor (column 6 lines 13-18) adapted to sense physiological conditions adjacent to the elongated tube and disposed within the secondary lumen with an inner diameter of 10 French (column 3 lines 63-66) which is equal to approximately 3.3 mm or 0.131 inches.

12. Thus for claims 1-11, 13, and 15-27, Fonger et al discloses the claimed invention except for explicitly disclosing (a) the distally disposed pressure sensor embedded in a distal portion of the catheter and (b) the at least one wire having a proximal end mated to an external antenna. Purdy et al teaches (a) a distally disposed pressure sensor (94) embedded in a distal portion of the catheter (as best seen in Figure 14, 15, and 17) (paragraph 132) and (b) at least one wire having a proximal end mated to an external antenna (wire element 96, paragraph 133). The claims would have been obvious because the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Because both Fonger et al and Purdy et al teach pressure measurement catheters, it would have been obvious to one skilled in the art at the time of the invention to substitute one distally disposed pressure sensor configuration for the other to achieve the predictable results of measuring a pressure of fluid surrounding the distal portion of

the catheter via a distally disposed pressure sensor configuration in a pressure measurement catheter system.

13. Claims 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fonger et al in view of Purdy et al and in further view of Quackenbush (US 5,104,398). Fonger et al in view of Purdy et al discloses the claimed sensor catheter drainage system except for (a) the polymer selected from a group consisting of silicones, silicone-like materials, and polyurethanes and (b) the at least one wire is disposed within a secondary catheter coupled to the first that can be peeled apart to allow the catheter length to be adjusted independent the length of the secondary catheter. Quackenbush discloses a membrane splitting tube 10 comprised of polyurethane (column 3 line 23) with a catheter or wire inserted in an outer peel-away membrane (column 1 lines 33-41). The claim would have been obvious because a person of ordinary skill at the time of the invention would have a good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product is not of innovation but of ordinary skill and common sense. Thus, it would have been obvious to a person of ordinary skill in the art at the time of the invention to try using a polyurethane catheter with a secondary catheter or wire inserted in an outer peel-away membrane as taught by Quackenbush in an attempt to provide a catheter with a selectively adjustable length, as a person with ordinary skill has a good reason to pursue the known options within his or her technical grasp. In turn, because the catheter, wire, and secondary catheter as claimed have the properties predicted by the prior art, it would have been obvious to make a catheter having at least

one wire running therethrough, which is coupled to a sensor disposed at a distal portion of the catheter, and wherein an outer peel-away membrane is provided to selectively adjust the length of a catheter.

Response to Arguments

14. Applicant's arguments filed 01/02/2008 have been fully considered but they are not persuasive.

15. With respect to Applications assertions that "Applicant notes that in the July 19, 2007 Notice of Panel Decision from Pre- Appeal Brief Review, the panel agreed to withdraw the pending rejections and issue a new Office Action. However, in the new Office Action mailed October 4, 2007 the Examiner issues the same rejection that was withdrawn by the panel. Accordingly, while Applicant provides the following additional remarks in response to the pending rejections, Applicant believes that the rejections were already overcome.", the Examiner reiterates that (see paragraph 12 from the Non-Final Office Action mailed 10/04/2007) "Applicant's arguments, see pages 2-3, filed 04/27/2007, with respect to the rejection(s) of claim(s) 1-11, 13, and 15-27 35 U.S.C. 103(a) as being unpatentable over Fonger et al in view of Purdy et al have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, new ground(s) of rejection is made in view of a different interpretation of the previously applied reference and a new ground(s) of obviousness."

16. Applicant argues the 103(a) rejection of at least independent claims 1 and 18 as being unpatentable under Fonger in view of Purdy, specifically arguing:

(a) it would not be obvious to modify the device of Fonger to include the distally disposed pressure sensor embedded in a wall in a distal portion of the catheter as taught by Purdy because it does not yield a combination where each element performs the same function as it did separately, where to embed or dispose the sensor as taught by Purdy in a distal portion of the catheter as taught by Fonger would change the function performed by the sensor, and

(b) it would not be obvious to modify the device of Fonger to include the an antenna coupled to a proximal end of a wire extending through the catheter as taught by Purdy because there is no advantage to modify the cardiac output probe of Fonger to include an antenna as taught by Purdy because there is no need to remotely communicate with or energize the detector of Fonger.

17. The Examiner disagrees, maintains the rejection, and notes in response the following:

18. With regards to Applicant's argument (a), the Examiner notes the function of the sensors as taught by both Fonger and Purdy is to measure pressure and to substitute one distally disposed pressure sensor configuration for another achieves the predictable results of measuring a pressure of a fluid surrounding the distal portion of the catheter via a distally disposed pressure sensor configuration in a pressure measurement catheter system, thus to substitute the pressure sensor configuration as taught by Fonger by embedding the pressure sensor configuration as taught by Purdy in a distal portion of the catheter as taught by Fonger would not change the function performed by the sensor because both the sensors configurations function to measure pressure.

19. With regards to Applicant's argument (b), the Examiner notes the advantage or rationale to substitute the hardwired data communications of Fonger with the wireless data communications including an antenna of Purdy is to achieve the predictable results of measuring a pressure of a fluid surrounding the distal portion of the catheter via a distally disposed pressure sensor configuration in a pressure measurement catheter system. Moreover the Examiner notes that one of ordinary skill in the art at the time of the invention would be knowledgeable of the substitution or replaceability of various configurations of data communication aiding in measuring pressure, each providing a means for the transmission of data in pressure measurement.

Conclusion

20. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY G. HOEKSTRA whose telephone number is

(571)272-7232. The examiner can normally be reached on Monday through Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/J.H./
Jeff Hoekstra
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736